DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Memorandum

Date: November 19, 2003

To: Oncologic Drugs Advisory Committee Members and Guests

From: Richard Pazdur, M.D.
Director, Division of Oncology Drug Products, CDER, FDA

Subject: FDA Background Package for December 16, 2003 Meeting

---

This memo outlines the purpose of the December meeting of ODAC and describes the contents of this briefing package.

The Food and Drug Administration is undertaking a project to evaluate potential endpoints for cancer drug approval. Endpoints will be examined for the most common cancers, such as lung cancer, colon cancer, etc. For each cancer, FDA will hold public workshops to identify important issues, and these issues will be discussed in meetings of the Oncologic Drugs Advisory Committee (ODAC). Subsequently, guidance documents will be published describing FDA's current thinking on endpoints for cancer drug approval.

Both the morning and afternoon sessions of the December 16th meeting will address cancer endpoints. In the morning, general cancer endpoint issues will be discussed, especially the role of time to progression. The afternoon session will focus on endpoints in lung cancer. The afternoon session will include presentations from partipants in the lung cancer endpoint workshop held April 15, 2003. ODAC discussions will center on FDA written questions, which you should receive in about two weeks.

Documents in this background package include:

General background documents:

- TAB 1 Endpoints that have supported cancer drug approval (JCO article)
- TAB 2 FDA efficacy guidance
- TAB 3 Cancer supplemental applications guidance

Lung Cancer Endpoints

- TAB 4 Executive summary of workshop discussion
- TAB 5 1990 FDA guideline on drug approval in lung cancer

Please also refer to the FDA endpoints web page for additional background documents and slides from the April lung cancer workshop presentations
http://www.fda.gov/cder/drug/cancer_endpoints/default.htm